Rep. Camille Y. Lilly

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AMENDMENT TO HOUSE BILL 4327

AMENDMENT NO. _____. Amend House Bill 4327 by replacing everything after the enacting clause with the following:

"Section 1. Short title. This Act may be cited as the 340B Transparency, Reporting, and Accountability Act.

Section 5. Findings. The General Assembly finds that:

(1) The intent of the 340B Drug Discount Program is to provide discounted medicines to eligible healthcare organizations for the purpose of improving access to affordable medications for low-income, underinsured, uninsured, or otherwise vulnerable patients being treated at eligible hospitals, clinics, federally qualified health centers (FQHC), and safety-net hospitals in or adjacent to vulnerable communities.

(2) Congress intended the 340B Drug Discount Program to provide discounts only to federally-funded clinics and

qualified hospitals that provide direct clinical care to uninsured Americans who meet the definitions of vulnerable communities and vulnerable patients.

(3) The appropriate and effective use of the 340B Drug Discount Program is essential for improving health outcomes, particularly for vulnerable and underserved communities in rural, suburban, and urban areas throughout Illinois meeting the definitions of vulnerable communities and vulnerable patients.

(4) There is a need for increased, consistent, statewide data to evaluate program utilization, financial impact, and patient benefits. Increased transparency in aggregate financial and operational reporting enhances legislative oversight without interfering with federal law. Increased transparency is needed to ensure that vulnerable communities receive the benefits intended from the Patient Access to Pharmacy Protection Act.

(5) To protect vulnerable communities, the General Assembly must pass the Health Equity Infrastructure Access and Stabilization Act. This includes creation of and funding of the following components:

(A) the Vulnerable Community Health Capital Fund Voluntary investment program;

(B) the Community Health Networks of Continuum Care;

(C) the Illinois Safety Net Hospital Package;

(D) the Behavioral and Mental Health (BMH) Access and Expansion Fund;

(E) the Stabilization and Sustainability Operational Funding Program;

(F) the 340B Grantee Contract Pharmacy Access Act integration;

(G) sustainable funding opportunities through transparency of the 340B Federal Program; and

(H) the Unified Health Equity Omnibus Package.

(6) Revenues associated with the federal 340B Drug Discount Program may support the financial stability of hospitals, federally qualified health centers, Ryan White providers, rural providers, and other historical safety-net institutions serving vulnerable communities experiencing health care access shortages, provider scarcity, or risk of service reduction or closure.

(7) Vulnerable communities in the State of Illinois are populations or geographic areas whose residents experience disproportionate barriers to achieving optimal health outcomes due to cumulative social, economic, environmental, and structural disadvantages. These communities are characterized by elevated health disparities, limited access to health care services, and increased exposure to risk factors, such as poverty, inadequate insurance coverage, geographic isolation, systemic discrimination, and unmet social determinants of

health, including housing, transportation, food security, and environmental conditions, and who, as a result of these conditions, experience reduced access to timely, culturally competent, and geographically proximate community-based hospital and health care services.

(8) This Act is intended solely to establish a state-level reporting and transparency framework and shall not regulate pricing, reimbursement, or participation in the federal 340B Program.

(9) This Act is intended as a step toward either annual or biennial 340B covered entity reporting.

Section 10. Definitions. As used in this Act:

"340B covered entity" or "covered entity" means a covered entity as defined in 42 U.S.C. 256b(a)(4), with a service address in Illinois as of January 1 of the reporting year.

"340B Drug Discount Program" means the program established under Section 340B of the federal Public Health Service Act, 42 U.S.C. 256b.

"340B entity type" means the designation of the 340B covered entity according to the entity types specified in 42 U.S.C. 256b(a)(4).

"340B identification number" means the unique identification number provided by the Health Resources and Services Administration to identify a 340B-eligible entity in the 340B Office of Pharmacy Affairs Information System.

"Contract pharmacy" means a pharmacy that enters into a contract with a 340B covered entity to provide services to the 340B covered entity's patients, including dispensing entity-owned 340B drugs.

"Reporting year" means the 12-month period to be covered by the report described in Section 15, as determined by the Department of Insurance.

"Pharmaceutical manufacturer" means an entity that is engaged in:

(1) the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis; or

(2) the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products.

"Pharmaceutical manufacturer" does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law.

"Vulnerable communities" include, but are not limited to:

(1) low-income and economically disadvantaged populations, including households below 80% of area median income;

(2) racial and ethnic minority populations and historically marginalized groups experiencing systemic

inequities;

(3) rural and medically underserved areas with limited provider access or hospital closures;

(4) communities facing environmental justice burdens, including high pollution exposure;

(5) populations with higher prevalence of chronic disease and poor health outcomes linked to social determinants of health; or

(6) individuals with disabilities, older adults, LGBTQ+ populations, and justice-involved individuals identified as equity-focused populations under Illinois law.

Section 15. 340B Drug Discount Program study.

(a) As soon as practical after the effective date of this Act, the Department of Insurance shall conduct a comprehensive study of how 340B covered entities within Illinois participate in the 340B Drug Discount Program. The study shall include an examination of the impact of this participation by 340B covered entities on State health programs, such as Medicaid and the State Employees Group Insurance Program. The study shall include, but not be limited to, an assessment of:

(1) with respect to each covered entity, the:

(A) name;

(B) service address;

(C) 340B identification number; and

(D) designation of entity type, as specified in 42 U.S.C 256b(a)(4);

(2) the amount of 340B revenue, defined as the total patient and payer reimbursement less the total 340B acquisition cost, generated by 340B covered entities from both self-administered and physician-administered drugs;

(3) the amount spent on third-party administrators for the management of the 340B Drug Discount Program;

(4) the amount paid to pharmacy benefit managers, as defined in subsection (a) of Section 513b1 of the Illinois Insurance Code, in contract pharmacy arrangements;

(5) the amount paid to contract pharmacies;

(6) whether each covered entity maintains title to 340B drugs in contract pharmacy locations;

(7) the average markup imposed by each covered entity on 340B-priced drugs;

(8) the aggregate and transaction-level dollar amount of discounts that each 340B covered entity passes to patients at the point of sale for both in-house and contracted pharmacies, as defined by the difference between the total reimbursement amount to the 340B covered entity and the 340B price;

(9) the aggregate and transaction-level acquisition cost paid by a 340B covered entity for all prescription drugs organized by therapeutic class obtained under the 340B Drug Discount Program and dispensed or administered

to patients;

(10) the aggregate and transaction-level payment amount received by a 340B covered entity for all drugs organized by therapeutic class obtained under the 340B Drug Discount Program and dispensed or administered to patients;

(11) the aggregate and transaction-level payment made to contract pharmacies to dispense drugs obtained under the 340B Drug Discount Program;

(12) the number of claims for prescription drugs described in paragraph (10) organized by therapeutic class of drug;

(13) how the 340B covered entity uses any savings from participating in the 340B Drug Discount Program, including the amount of savings used for the provision of charity care, community benefits (including identification of the benefit program), and any similar program of providing unreimbursed or subsidized health care;

(14) the aggregate and transaction-level payment made for any other administering expense for the 340B Drug Discount Program;

(15) the percentage of the 340B covered entity's claims that were for prescription drugs obtained under the 340B Drug Discount Program;

(16) the percentage of total patients of the 340B covered entity that were:

(A) served by a sliding fee scale for a prescription drug dispensed or administered under the 340B Drug Discount Program;

(B) Medicaid customers and uninsured or underinsured patients;

(C) racial and ethnic minority populations;

(D) patients residing in rural or Medically Underserved Areas, including Governor's Exceptions, designated by the Health Resources and Services Administration, an agency of the United States Department of Health and Human Services;

(E) populations with a higher prevalence of chronic disease and poor health outcomes linked to societal determinants of health; and

(F) individuals with disabilities, older adults, LGBTQ+ populations, and justice-involved individuals;

(17) the 340B covered entity's total operating costs;

(18) the 340B covered entity's total costs for charity care;

(19) a copy of the 340B covered entity's financial assistance policy for the reporting year;

(20) identification of the parties involved in the 340B procurement and dispensing process for each covered facility;

(21) the aggregate and transaction-level payment made to a pharmacy services administrative organization that

provides pharmacy services for a 340B contract pharmacy; and

(22) the aggregate and transaction-level payment made to a pharmacy benefit manager that provides pharmacy benefit management services for a 340B covered entity organized by therapeutic class of drug.

(b) The Department of Insurance may adopt rules as necessary to implement this Section.

(c) The Department of Insurance shall request the information described in subsection (a). All 340B covered entities, insurers as defined in subsection (a-5) of Section 513b1 of the Illinois Insurance Code, pharmacy benefit managers, third-party administrators, and administrative service organizations of the State Employees Group Insurance Program shall comply with requests for information relevant to subsection (a) from the Department of Insurance in the format prescribed and within the timeframe specified. The Department of Insurance is hereby granted specific authority to fine any 340B covered entity, insurer, pharmacy benefit manager, third-party administrator, or administrative services organization that fails to comply with this Section within 14 calendar days after the due date specified by the Department of Insurance, at a rate of $100 per day for each day beyond 14 calendar days for federally qualified health centers and historical safety-net hospitals, and at a rate of $1,000 per day for each day beyond 14 calendar days for all other

entities, that the information is past due. Fines collected pursuant to this subsection shall be deposited into the Vulnerable Community Hospital Capital Investment Fund, which is hereby created as a special fund in the State treasury. The Department of Insurance shall enforce this Section pursuant to the powers granted to it by law, including, but not limited to, the powers provided under Article XXIV of the Illinois Insurance Code. Subsections (2) through (5) of Section 403A of the Illinois Insurance Code shall apply to the imposition of any fine.

(d) Subject to subsection (e), the Department of Insurance shall maintain the confidentiality of any information submitted under subsection (c) for which the submitting person or entity includes a request that meets the criteria in paragraph (g) of subsection (1) of Section 7 of the Freedom of Information Act, and the information shall not be subject to subpoena in any private civil litigation in this State. Nothing in this Section shall prevent the Department of Insurance from furnishing information collected from 340B covered entities to State or federal authorities that may investigate, prosecute, or pursue other legal action against a 340B covered entity for violations of 42 U.S.C. 256b or any applicable State law.

(e) The Department of Insurance shall submit a report of the findings of its study to the General Assembly and to the Governor by July 1, 2028. The report shall provide findings

aggregated across 340B covered entities and shall not disclose information or data attributed to any specific 340B covered entity. The report shall address whether the data collected by the Department indicates a need for annual or biennial reporting by 340B covered entities. The report may include any aggregated findings related to the populations identified in paragraph (16) of subsection (a).

Section 95. Repeal. This Act is repealed on July 1, 2029.

Section 900. If and only if House Bill 2371 of the 104th General Assembly becomes law, then the Patient Access to Pharmacy Protection Act is amended by changing Section 40 as follows:

(10400HB2371sam002, Sec. 40)

Sec. 40. Enforcement.

(a) The Attorney General is authorized to enforce this Act ~~under its general authority under the Attorney General Act~~. If the Attorney General has reasonable cause to believe that there is or has been a violation of Section 15 of this Act, then the Attorney General may commence a civil action in the name of the People of the State of Illinois to enforce the provisions of this Act in the appropriate circuit court.

(b) Upon finding a violation of Section 15 of this Act, a court may order:

(1) temporary, preliminary, or permanent injunctive relief for any act, policy, or practice that violates this Act;

(2) money damages to be paid to the 340B covered entity as a result of the violation of this Act;

(3) the assessment of a civil penalty of up to $1,000 per violation for each violation of Section 15; or

(4) any other relief.

(c) A civil penalty imposed or a settlement or other payment made pursuant to this Act shall be made payable to the Attorney General's State Projects and Court Ordered Distribution Fund.

(Source: 10400HB2371sam002.)

Section 905. The State Finance Act is amended by adding Section 5.1038 as follows:

(30 ILCS 105/5.1038 new)

Sec. 5.1038. The Vulnerable Community Hospital Capital Investment Fund.

Section 999. Effective date. This Act takes effect upon becoming law, but this Act does not take effect at all unless House Bill 2371 of the 104th General Assembly, as amended by Senate Amendment No. 2, becomes law.".